

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
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# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference  5853-449WO		Date of mailing (day/month/year)  16/03/2005	
International application No.  PCT/US05/10112	International filing date (day/month/year)  25 March 2005 (25.03.2005)	Priority date (day/month/year)  26 March 2004 (26.03.2004)	
International Patent Classification (IPC) or both national classification and IPC  IPC(7): A61B 5/055 and US CL: 424/9.3, 9.32			
Applicant  UNIVERSITY OF FLORIDA RESEARCH FOUNDATION, INC.			

1. This opinion contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the opinion
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US  Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Michael G. Hartley Telephone No. (703) 308-1235  <i>Janice Ford</i> <i>703</i>
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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/10112

**Box No. 1 Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

a sequence listing

table(s) related to the sequence listing

b. format of material

in written format

in computer readable form

c. time of filing/furnishing

contained in international application as filed.

filed together with the international application in computer readable form.

furnished subsequently to this Authority for the purposes of search.

3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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INTERNATIONAL SEARCHING AUTHORITY

International application No.  
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**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-31</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-31</u>	NO
Industrial applicability (IA)	Claims <u>1-31</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-31 lack novelty under PCT Article 33(2) as being anticipated by GRINSTAFF (US 5,498,421). GRINSTAFF discloses a method of assessing oxygenation comprising administering a contrast agent comprising PEG or pyridoxal phosphate modified hemoglobin and performing MRI imaging, see column 29, lines 28-42, column 26, lines 212-61 and examples 18-19. The contrast agents may further include various paramagnetic metals to enhance the MRI image, see column 7, lines 11-14. The hemoglobin contrast agents also may include various surfactants as claimed, see column 12, lines 14+. The contrast agents may further include a perfluorocarbon in the core of microparticulate contrast agents, see column 27.

Claims 1-31 lack an inventive step under PCT Article 33(3) as being obvious over GRINSTAFF discloses a method of assessing oxygenation as set forth above. It would have been obvious to one of ordinary skill in the art to employ any of the contrast agents, surfactants, metals, etc., taught by GRINSTAFF because the various components of the contrast agents are taught by GRINSTAFF to be interchangeable for optimizing the imaging capabilities for various purposes, including assessing the oxygenation of tissues.

Claims 1-31 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.